

EXHIBIT B

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF ARIZONA

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4 -----x

5 IN RE BARD IVC)

6 FILTERS PRODUCTS) NO. MD-15-02641-PHX-DGC

7 LIABILITY LITIGATION)

8 ----- X

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11 DO NOT DISCLOSE - SUBJECT TO FURTHER

CONFIDENTIALITY REVIEW

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13 VIDEOTAPED DEPOSITION OF CHRISTINE L. BRAUER, Ph.D.

14 WASHINGTON, D.C.

15 WEDNESDAY, AUGUST 2, 2017

16 9:07 A.M.

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24 Reported by: Leslie A. Todd

1 patients were advised of the details of that
2 migration?

3 A Yeah, I cannot recall if that was the
4 Ethics Committee request or the request of the
5 investigator in Bard. I -- I -- I cannot recall
6 whose idea that was --

7 Q Right.

8 A -- sitting here today.

9 Q But neither -- but regardless of who --
10 whose idea it was, you didn't see any evidence
11 that FDA was advised that the investigator, the
12 Ethics Committee, a physician on behalf of Bard
13 that was monitoring the study, stopped the study
14 for the purpose of giving the rest of the patients
15 detailed informed consent about that migration?

16 A I don't recall if that detail was in the
17 510(k) or not.

18 Q How about --

19 A I recall the fracture and the particular
20 patient being described in the 510(k).

21 Q Was FDA advised -- well, let me ask you,
22 what -- what effect on the clearance of the
23 Recovery filter do you think it would've had on
24 whoever was looking at the 510(k) application for

1 the Recovery filter had he or she known that the
2 investigator thought that all the patients should
3 be advised of the circumstances of that migration
4 before the study could continue?

5 A Personally?

6 Q Yeah.

7 A I don't believe it would have had much
8 of an impact. Fracture was a well-known risk for
9 IVC filters, and the event was clearly described
10 in the 510(k) application. If anything, I think
11 that -- you know, at least if I had been at FDA, I
12 would have been happy to see that some
13 precautionary steps were taken.

14 Q Okay. That's your opinion, I
15 understand. But you can't tell me what effect
16 that would have had on the actual person looking
17 at the application, true?

18 A You're correct, sir, I cannot speculate
19 on what any individual would do or not do.

20 Q I would have to ask him or her.

21 A Yes, sir.

22 Q And the same question with respect to
23 the fracture, that the fracture -- the fractures
24 were of the type and quality that caused whoever